

REMARKS

Claims 2-5 and 7-27 are active. New claims 26-27 find support in paragraph [0009] at the top of page 5 of the specification. These claims require that the dentrifice contains powder cellulose *per se* and not particles or other solid components made using powder cellulose as an ingredient. The Applicants thank Examiner Welter for withdrawing the prior objections and rejections and for considering the new information disclosure statement. The new rejections under 35 U.S.C. § 103 are addressed below.

Rejection—35 U.S.C. §103(a)

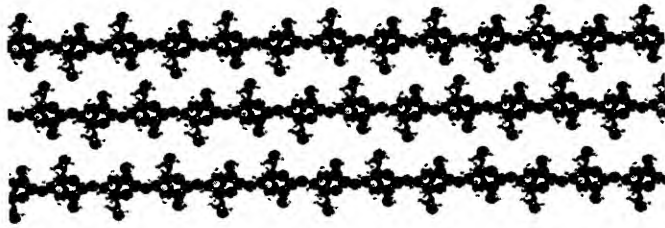
Claims 2, 3, 5, 7-17 and 19-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP 11-199456, in view of Satoshi, et al., JP 01-299211 (abstract).

Prior art does not teach all elements of the invention

To establish a *prima facie* case for obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Here, the Examiner has not established that either JP ‘456, which teaches crystalline cellulose, or Satoshi, et al., disclose the powder cellulose element required by claim 2.

Independent claim 2 requires “(A) powder cellulose”. JP ‘456 does not teach this element of the invention but is instead directed to “crystalline cellulose”, which has different properties because it is produced by partial depolymerization of cellulose, while powdered cellulose is made by mechanical disintegration, see *European Pharmacopoeia* (entries for “Cellulose, Microcrystalline” and “Cellulose, Powdered” attached).

Because of how it is made, microcrystalline cellulose has a higher degree of crystallinity¹ and different cellulose strands can easily hydrogen bond.



On the other hand, powdered cellulose has more amorphous parts² due to its production by mechanical means which would interfere with orderly hydrogen bonding between cellulose strands. These differences in origin and structure impart different functional properties on microcrystalline and powdered cellulose as shown by Fechner, et al., AAPS PharmSci (2003) 5(4) (attached). Furthermore, while not being bound to any particular theory, it is considered that the three-dimensional structure formed by a combination of powder cellulose having a large degree of polymerization and the granules according to the invention would strengthen the film structure of foam. Crystalline cellulose having a smaller value in its degree of polymerization would not form such a foam structure and thus would not contribute to the foaming property as compared to powder cellulose.

Satoshi is relied upon for teaching another element (granules) of the invention, but does not disclose or suggest “(A) powder cellulose” as required by claim 2.

Moreover, in view of the recognized differences in structure and functional properties of crystalline and powder cellulose one of ordinary skill in the art would not have had a reasonable expectation of success in obtaining the dentifrice composition of the invention

¹ See Fechner, et al., AAPS PharmSci (2003) 5(4) (attached) *Introduction*: “Microcrystalline cellulose (MCC) has a higher degree of crystallinity because it is usually obtained by partially hydrolyzing cellulose with mineral acid.”

² See Fechner, et al., AAPS PharmSci (2003) 5(4) (attached) *Results of FT-Raman Spectroscopy* “As expected, most bands of the PC spectra were broader than MCC bands because PC contains a higher amount of amorphous parts.”

having superior foaming properties described above based on the teachings of JP '456 or Satoshi, neither of which teaches the powder cellulose element of the invention.

Prior art did not recognize how to improve foaming properties

While it was known to add crystalline cellulose to a dentrifice composition as a diluent (see Satoshi, paragraph [0037]) or to provide a cleaning effect (see JP '456, paragraph [0016], the prior art did not know how to improve the foaming property of a dentrifice by combining powder cellulose and the granules required by claim 2. Neither of these references describes or suggests that foaming properties would be improved by combining powder cellulose and the granules required by the invention. One of ordinary skill in the art would not have expected such an improvement in foaming properties based on JP '456 which doesn't teach powder cellulose and is silent about its foaming properties when combined with the appropriate kind of granules.

The Applicants have already demonstrated the superior foaming properties of this combination in the prior-filed declaration of Mr. Hidenori Yoshida. Toothpaste compositions were prepared but with variations in the content and nature of surfactant and silica granules as detailed in the table below. The foaming quality and quantity was analyzed using the techniques reported in example 15 of the specification. The data along with the data from example 15 and comparative example 7 from the specification are reproduced below:

| | surfactant | Silica granules | Foam volume ^a | Texture of Foam | Wateriness of Foam | Viscosity of Foam | Foaming Property |
|----|--------------------------------|---------------------------------|--------------------------|-----------------|--------------------|-------------------|------------------|
| 15 | Sodium lauryl sulfate 1.5 wt.% | Silica granules 2.5 wt.% 200 µm | 61 | 5 | 6 | 3 | 3 |
| 1 | Sodium lauryl sulfate 1.5 wt.% | 2.5 wt.% 100 µm | 65 | 7 | 6 | 4 | 4 |
| 2 | Sodium lauryl sulfate 1.5 wt.% | 2.5 wt.% 400 µm | 60 | 4 | 5 | 4 | 6 |
| 3 | Sodium lauryl sulfate 0.2 wt.% | 2.5 wt.% 200 µm | 58 | 3 | 5 | 3 | 4 |
| 4 | PEO (200) PPO(40)block | 2.5 wt.% 200 µm | 58 | 4 | 6 | 3 | 6 |

| | | | | | | | |
|-----------|--|----------------------|----|----|---|---|---|
| | copolymer type nonionic surfactant (HLB 16) 4.5 wt. % | | | | | | |
| 6 | Sodium lauryl sulfate 1.5 wt. % | 25.0 wt. % 200 µm | 63 | 6 | 7 | 5 | 6 |
| 7 | Acyl amino acid salt 1.5 wt. % | 2.5 wt. % 200 µm | 57 | 4 | 5 | 3 | 4 |
| C ex 7 | Sodium lauryl sulfate 1.5 wt. % | - | 56 | -1 | 4 | 1 | 2 |

^a mL of foam after 1 minute

These data provide evidence of an *enhancement in foaming quantity* and quality for the combination of surfactant, powdered cellulose and silica of specified size for a breadth of composition in which the surfactant content is ranged from 1.5-4.5 wt. %, the nature of the surfactant is demonstrated for anionic and nonionic surfactants and for a content of silica granules ranging from 2.5 to 25.5 wt. % and particle size range of 100 to 200 µm. Such evidence is offered in rebuttal to any *prima facie* case for obviousness because none of the cited references disclose or suggest an enhancement in foam quantity and quality resulting from the combination of powdered cellulose, surfactant and granules of specified size.

In further support of the argument above, the new attached Declaration shows that compositions containing *only* powder cellulose (but not granules) or *only* granules (but not powder cellulose) to not attain the foaming properties of the combination of the invention. That is, the combination of both powder cellulose and the granules is required to attain these properties.

[Table 1A]

| | Ex. 1 | Comp. Ex. 1' | Comp. Ex. 2' | Comp. Ex. 3 | Comp. Ex. 4 |
|--|-------|--------------|--------------|-------------|-------------|
| Sodium fluoride | 0.20 | 0.20 | 0.20 | 0.20 | 0.20 |
| Polyethylene glycol (PEG600) | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 |
| Glycerin | 20.00 | 20.0 | 20.00 | 20.00 | 20.00 |
| Sorbitol | 30.00 | 30.00 | 30.00 | 30.00 | 30.00 |
| Silica granules (average particle size of 200µm) | 2.50 | - | 2.50 | - | 2.50 |

| | | | | | |
|--|---------|---------|---------|---------|---------|
| Silica powder | 18.50 | 18.50 | 18.50 | 18.50 | 18.5 |
| Powder cellulose | 0.5 | - | - | 0.5 | - |
| Crystalline cellulose | - | - | - | - | 0.5 |
| Xanthan gum | 0.40 | 0.4 | 0.40 | 0.40 | 0.40 |
| Carrageenan | 0.60 | 0.6 | 0.60 | 0.60 | 0.60 |
| DL-Malic acid | 2.00 | 2.00 | 2.00 | 2.00 | 2.00 |
| Sodium lauryl sulfate | 1.50 | 1.50 | 1.50 | 1.50 | 1.50 |
| pH Regulator (adjust pH to 6.0 with NaOH) | q.s. | q.s. | q.s. | q.s. | q.s. |
| Flavor | 1.40 | 1.40 | 1.40 | 1.40 | 1.40 |
| Purified water | Balance | Balance | Balance | Balance | Balance |
| Total | 100 | 100 | 100 | 100 | 100 |

[Table 2A]

Evaluation of foam quality (N=5)

| | Texture of foam | Wateriness of foam | Viscosity of foam | Foaming property |
|------------------------|-----------------|--------------------|-------------------|------------------|
| Example 1 | 4 | 4 | 5 | 5 |
| Comparative Example 1' | 0 | 3 | 1 | -1 |
| Comparative Example 2' | -1 | -2 | 0 | 0 |
| Comparative Example 3 | 5 | 4 | 5 | -1 |
| Comparative Example 4 | 0 | -2 | 0 | 1 |

As is evident from Table 1A and 2A, the dentifrice composition of the present invention was remarkably excellent in foaming property and foam quality, as compared with the composition comprising no powder cellulose or granules (Comp. Ex. 1'), the composition comprising no powder cellulose (Comp. Ex. 2'), the composition comprising crystalline cellulose in place of powder cellulose (Comp. Ex. 4). Further, the composition of the present invention was particularly excellent in foaming property, as compared with the composition comprising no granules (Comp. Ex. 3). The prior art did not provide a reasonable expectation of success for a dentifrice having these superior foaming properties.

Therefore, since the prior art did not teach all the elements of the invention, namely powder cellulose, and did not suggest a combination of carefully selected ingredients that

provides the superior foaming properties (both qualitative and quantitative) attained by the invention, this rejection cannot be sustained.

Rejection—35 U.S.C. §103(a)

Claims 2, 3, 7-20 and 22-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Koichi, et al., JP 2003-081796, in view of Satoshi, et al., JP 01-299211 (abstract) as evidenced by “HLB Values”. While Koichi, teaches “powder state cellulose” and “crystalline cellulose” (see paragraph [0037]) as excipients, it does not teach powder state cellulose in combination with “(D) granules having a particle size permitting passage of a 30-mesh sieve but not permitting passage of a 200-mesh sieve” as required by claim 2. The OA admits that Koichi fail to teach these granules at the bottom of page 7.

Satoshi is again applied for teaching granules “to increase abrasive power” (OA, p. 8, lines 4-5). However, neither of these references provides a reasonable expectation of success for the superior foaming properties attained by the invention such as those described in the prior-filed Declaration as well as the Declaration attached to this response. Consequently, this rejection cannot be sustained.

Rejection—35 U.S.C. §103(a)

Claims 5 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Koichi, et al., JP 2003-081796, in view of Satoshi, et al., JP 01-299211 (abstract) as applied to claims 2, 3, 7-20 and 22-25 above and further in view of JP 11-199456, as evidenced by “HLB Values”. Koichi and Satoshi have been distinguished above. Neither suggests formulating the specific combination of ingredients required by claim 2, nor does either give any indication that such a combination of ingredients would have provided the superior

foaming properties attained by the invention and evidenced by the specification and the declarations of record.

JP '456 was relied upon for teaching "0.5 wt% crystalline cellulose powder with a particle size of 60 μm ", OA, p. 10, lines 1-2. However, it does not teach powder cellulose, nor does it provide any motivation for combining the specific ingredients required by the claims or expectation that such a combination would achieve the superior foaming properties demonstrated for the invention. Consequently, this rejection cannot be sustained.

Rejection—35 U.S.C. §103(a)

Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Koichi, et al., JP 2003-081796 or JP 11-199456, in view of Satoshi, et al., JP 01-299211 (abstract) and further in view of Hiroaki, et al., JP 09-295947, as evidenced by "HLB Values".

Koichi, Satoshi and JP '456 have been distinguished above. None of these suggests formulating the specific combination of ingredients required by claim 2, nor do they provide any indication that such a combination of ingredients would have provided the superior foaming properties attained by the invention and evidenced by the specification and the declarations of record.

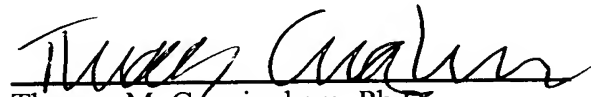
Hiroaki was relied upon for teaching "microspherical particles with a diameter of 0.8-1 mm" (OA, p. 11, 2nd paragraph). However, it does not provide any motivation for combining the specific ingredients required by the claims or expectation that such a combination would achieve the superior foaming properties demonstrated for the invention. Also, while the microspherical particles of Hiroaki may contain powder cellulose, since the powder cellulose forms a part of the particle it would not be in a form suitable for interacting with the granule component of the invention and would not provide the same foaming properties. Consequently, this rejection cannot be sustained.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Richard L. Treanor

A handwritten signature in black ink, appearing to read "Thomas M. Cunningham", is written over a horizontal line.

Thomas M. Cunningham, Ph.D.
Attorney of Record
Reg. No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)